

## REMARKS

Claims 1-4, 23, 24, 28-31, 33-42 are pending in the instant application. Claims 22 and 41 have been withdrawn from consideration. Applicants propose amending claims 1 and 23. Reconsideration of the rejection is respectfully requested in view of the following remarks.

Method claim 42 was presented for the first time in Applicants' last response. The present Action does not indicate the status of this claim. Applicants respectfully request this indication of the status of this claim.

### **Claim Rejections 35 USC §103**

Claims 1-4, 23-24, 28-31 and 31-40 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application Publication US 2003/0146541 A1 to Nakamura et al. (hereinafter referred to as "Nakamura") in view of U.S. Patent Application Publication US 2001/0004693 A1 to Burkhead et al. (hereinafter referred to as "Burkhead"). Applicants respectfully traverse this rejection.

Applicants respectfully submit that neither Nakamura nor Burkhead, whether taken individually, or in permissible combination, discloses or suggests the claimed invention.

In response to Applicants' arguments, the Action stated, specifically in Paragraph 3(A), "the present claims do not require that the entire device (both head and shank) must have the same axis of molecular orientation (i.e., along the longitudinal direction). Therefore, the mere fact that the direction of the molecular orientation in the reshaped head portion of the NAKAMURA devices may differ from the direction of molecular orientation in other portions of the device is irrelevant."

The Action did not argue with Applicants' characterization of the molecular orientation in the head portion of NAKAMURA's device splaying out in directions away from the longitudinal axis. Rather, the Action argues that this is not a basis for Applicants to argue for a difference between the claimed device and that of NAKAMURA because Applicants' present claims do not require that both the head and shank portions of the device have the same axis of molecular orientation.

The Action argues that independent claims 1 and 23 are open to multiple longitudinal axes.

Applicants respectfully traverse this characterization/conclusion. Applicants respectfully submit that the claimed device is required to have the same axis of molecular orientation for the head as for the shank portion of the device because the claimed device is required to have the same longitudinal axis for the head as well as the shaft portions. Applicants respectfully submit that a plain reading of the claim would indicate that the head and the shank do so have the same

longitudinal axis. Specifically, the claim reads in part, "...wherein said head portion and said shank portion are arranged on a longitudinal axis..." The phrase "**arranged on**" is also significant. (Applicants' boldface and underscoring for emphasis) Furthermore, there would be no point or purpose in stating "the head and shank portions are arranged on a longitudinal axis" if different axes were implied.

Thus, applicants respectfully submit that independent claims 1 and 23 *inherently* refer to a single or common longitudinal axis, and a single or common axis of molecular orientation.

In an excess of caution, however, Applicants propose to amend claims 1 and 23 to expressly recite that the head and shank portions are arranged on the same longitudinal axis. Applicants respectfully submit that the amendment to recite a "**common** longitudinal axis" can be accepted at this stage of prosecution. In particular, the claim requires no further search or consideration because the proposed amendment merely clarifies without creating new limitations. Specifically, the examiner's previous search and consideration of "...arranged on *a* longitudinal axis..." seemingly would have already encompassed "...arranged on a *common* longitudinal axis..." This amendment finds support in the specification at, for example, Paragraph [0059]. Although the word "common" here is applied in the context of the stages of manufacturing (e.g., process steps), it should be clear that process steps having a common longitudinal axis will yield a product having a common longitudinal axis.

The Action states in Paragraph 3(F) that Applicant argues that BURKHEAD fails to suggest the claimed invention because the BURKHEAD devices fail to have a longitudinal axis. The Action then states "the BURKHEAD devices are explicitly drawn and stated to have a "long axis" (paragraph 0028), which one of ordinary skill in the art as being equivalent to the claimed longitudinal axis."

Applicants respectfully traverse this characterization. A close reading of paragraph 0028 of BURKHEAD indicates that the head portion is not considered to be part of the long axis: "In some advantageous embodiments of this invention the orientation and/or reinforcing elements of the self-reinforced structure are mainly oriented in the direction of the long axis of the shaft of the implant (FIG. 4A) and may turn smoothly and continuously into the hook-like or hoe-like portion, as is shown in the schematic cross-sectional FIG. 4E." Applicants respectfully submit that "long axis" here refers to the shaft, not to the hook-like or hoe-like portion of the device. That is, the "longitudinal axis" of BURKHEAD pertains only to the shaft portion of the device. In contrast, the claimed "longitudinal axis" applies to **both** the head and shank portion of the claimed device; that is, both the claimed head and shank are part of the claimed longitudinal axis.

Thus, even if BURKHEAD discloses more molecular orientation in the shaft portion than in the head portion of his device, the combination with NAKAMURA still fails to remedy the deficiencies of NAKAMURA. In particular, the combination fails to disclose or suggest a device having a common longitudinal axis featuring a common axis of molecular orientation. Again, in NAKAMURA, the deformation of the head portion will splay the molecular

orientation in the head in directions away from the longitudinal axis. As for BURKHEAD, he does not consider the heel-like or hoe-like portion to be part of the long (or longitudinal) axis because the axis of the heel or hoe portion (to the extent it can be called an axis) is in a different direction from the long axis of the shank portion. Therefore, the heel or hoe portion of BURKHEAD does not share a common longitudinal axis with the shaft portion.

Accordingly, Applicants respectfully request that this rejection be withdrawn.

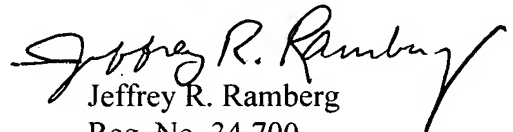
#### CONCLUSION

Neither the NAKAMURA nor BURKHEAD devices feature a common longitudinal axis having a common axis of molecular orientation, and neither NAKAMURA nor BURKHEAD can remedy the deficiencies of the other in this regard. This common alignment is significant, among other reasons, because it makes for a device of greater strength than it would be otherwise.

In view of the above remarks, Applicants respectfully submit that the present application is in condition for allowance. Accordingly, Applicants respectfully request issuance of a Notice of Allowance directed to claims 1-4, 23, 24, 28-31, 33-40 and 42.

Should the Examiner deem that any further action on the part of Applicants would be desirable, the Examiner is invited to telephone Applicants' undersigned representative.

Respectfully submitted,

  
Jeffrey R. Ramberg  
Reg. No. 34,700

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c/o Kensey Nash Corporation  
735 Pennsylvania Drive  
Exton, PA 19341  
Tel: (484) 713-2140  
Fax: (484) 713-2909